



GUGGISBERG CHEESE, INC.

Home of the Original Baby Swiss

U.S. Food and Drug Administration
Steve Rabe
6751 Steger Drive
Cincinnati, Ohio 45237

November 4, 2005

Copy
mailed 12/8/05
gfg

Dear Steve,

Guggisberg Cheese, Inc. purchased the old Union Cheese facility in 1996 and the building went under renovation to bring the plant up to the Code of Federal Regulations. Regarding the injunction (case NO. 5:95CV801) on the Union Cheese facility, I would like to formally request pursuit of vacating the injunction. During the recent FDA inspection Guggisberg Cheese, Inc. was made aware this request needs to go through the courts and we plan to follow through on this venture. I would like to provide the FDA Cincinnati District with information regarding the extensive steps that Guggisberg Cheese has taken to prevent adulteration of food products manufactured at this location. Enclosed is a brief outline of our Food Safety Programs.

I believe that the plant improvements, procedures implemented, employee training, and our current Quality Programs allow Guggisberg Cheese, Inc. to manufacture safe food products. For further information please contact me at 330-893-2500 or email at richard@babyswiss.com. Additional information regarding our food safety programs contact Jennifer George at 330-893-2500 or email at jenngeorge@guggisberg.com.

Sincerely,

Richard Guggisberg
President
Guggisberg Cheese, Inc.

Guggisberg Cheese, Inc. Food Safety Program:

Qualified professional in charge of sanitation: Jennifer George

The Quality Assurance Manager has a B.S. in microbiology, Certified in Food Protection by the ODH (cert# 32847), certified for drug confirmation for Beta-Lactam by ODA, and has taken an accredited HACCP course by the International HACCP Alliance.

Jennifer George has 10 years quality assurance experience in the dairy industry, a year of medical laboratory experience, and has attended sanitation courses from Diversey Lever and Silliker.

Training Program:

QA Manager conducts sanitation, GMP, laboratory, and procedural training. These training programs include blood borne pathogens, food borne pathogens, personal hygiene, cross contamination, effective sanitation, chemical safety, HACCP, milk receiving, and foreign material. The food borne pathogen training educates employees about *Listeria Monocytogenes*, pathogenic *E.coli*, and *Salmonella*; the best prevention is education.

New hires receive GMP's and watch sanitation videos.

Supervisors train employees on their specific job duties and a written SSOP manual is available. Retraining on specific items is done when procedures are modified and/or if inadequate job performance.

Continuous Improvement Program:

Facility was renovated prior to operation and a continuous program is in place to maintain proper upkeep of the plant. New cooler and warm cellars were built, reconstruction of floors and drains, old silo replaced with new one, additional CIP systems, program updates, and new security program are some examples of the continuous improvement projects that have been completed.

Audits:

Monthly internal auditing program by QA manager- These audits provide a list of items that need corrected and establishes who is responsible for correction. Follow up inspection to confirm correction is complete is dated on report.

ODA does plant inspections twice a year, HTST calibrations twice a year, split samples once a year, lab surveys biannually, and milk/product sampling monthly for micro.

USDA does annual inspection as a third party audit. Equipment sanitation and facility sanitary design are inspected. Inspection reports indicate corrected items.

FDA- inspected the plant in 2004 and 2005 with no negative findings. In 2004 two cheese samples were taken for pathogen testing and the results were acceptable.

Customer audits frequency depends on the individual company. Most customers request a plant inspection and program evaluation before approving Guggisberg Cheese as a supplier. Typically once a year a customer does a private audit.

GMP Third Party audits by an approved auditing firm is intended to start in the year 2006. Silliker GMP audit will inspect HACCP & prerequisite programs, documentation, employee practices, and overall plant sanitation. This will be a biannual program.

Quality monitoring:

Equipment- ChemServe reports are weekly checks for CIP systems and equipment cleaning that is documented in monthly report. ATP swabs of equipment are taken by the ChemServe representative to verify proper cleaning techniques. ChemServe makes corrections if deviations are noted and will retrain employee on proper technique if necessary. Each department does PRE-OP checks to confirm that equipment and surroundings was checked for sanitary conditions prior to start up. Sanitizer solutions are documented where applicable.

Ingredients- raw milk loads are tested for drug residue prior to unloading into the silos. Silo milk is monitored for dmc/dmscc, SPC, and components. Pasteurized milk is tested for coliforms and SPC daily to verify quality. Cheese is tested for pH, fat, and moisture. Brine is checked daily for salinity and weekly for coliforms, yeast&mold, and SPC to verify that the ozonation system is effectively disinfecting the brine. Water is tested monthly for coliforms using the IDEXX Colisure method for validation of potable water.

Finished product- is tested for coliform/e.coli Petrifilm per lot. Coliforms are the indicator organism uniformly used by the food industry to monitor sanitation effectiveness. Swiss composites samples from a days production are sent to an outside certified laboratory for micro testing. Out of specification lots are investigated to find source of problem.

Environmentals:

Air quality is monitored by monthly air sediment plates for yeast and mold.

Listeria spp. sampling program is designed to be a broad spectrum approach to detect possible environmental niches for that particular group of organisms. This is used as an environmental sanitation indicator because it is more sensitive. The idea is to eliminate the niche before *L.mono* takes up residence. Strict isolate detection doesn't indicate a problem until you have a major problem and then there is a higher risk of contamination through out the plant. The program aggressively looks for environmental niches at potentially neglected areas of the plant and major traffic flow sections. If positive environmental, the corrective action is to foam clean with chlorinated alkaline foam cleaner, foam sanitized with anionic/peracetic acid sanitizer; then the original site, including adjacent sites, are swabbed and submitted separately instead of a composite sample for verification that the area was corrected. If one of the recheck swabs is positive (which would identify the source) preventative action measures are taken to fix the problem and the swabs are done again for verification of correction. Swabs are taken outside of production zones where *Listeria spp.* would be common as a perimeter check. If perimeter is kept under control it reduces the risk of contaminates being tracked into the production areas. If perimeter has repeated positives then a control mechanism is put in place to reduce the risk of it entering the plant. (for example: foam foot baths using anionic/peracetic acid sanitizer at entrance from receiving bay and main plant entrance)

Correction of deviations:

The recent FDA inspection pointed out that the injunction on Union Cheese required *Listeria Monocytogenes* testing on equipment and finished product. This was done the first year of production for verification of correcting conditions of the plant. Guggisberg

Cheese operates under different processing conditions than Union Cheese and has sanitation controls that monitor sanitation, which creates a more sensitive monitoring system compared to random finished product samples specific for *Listeria Monocytogenes*. First of all Guggisberg Cheese pasteurizes milk according to the PMO to eliminate pathogens from the milk at the very beginning instead of completely relying on cultures and aging to eliminate pathogens. Secondly the brine is ozonated for microbial control. Finally a HACCP based system is in place and a validated sanitation program is in place. In light of the request for specific *Listeria Monocytogenes* testing to verify that production is continually sanitary, finished product samples and equipment swabs were sent out for pathogen testing to validate our sanitation program. Reports from certified laboratory are enclosed.

Pathogen testing HOLD and RELEASE program is in place to make sure contaminated product does not get out to the public. When a product and/or equipment is sampled and sent out for pathogen testing all vats made on that production date are placed on HOLD and does not get shipped out until cleared by QA.


SILLIKER, Inc.
Ohio Laboratory

 2057 Builders Place
 Columbus, OH 43204
 614/ 486 0150 Fax 614/ 486 0151

CERTIFICATE OF ANALYSIS

COA No:	OHI-30857514-0
Supersedes:	None
COA Date	9/30/05
Page 1 of 1	

TO:

 Ms. Jennifer B. George
 Quality Assurance Manager
 Guggisberg Cheese Inc.
 5060 State Route 557
 Millersburg, OH 44654

Received From:	Millersburg, OH
Received Date:	9/28/05

 Location of Test: (except where noted)
 Columbus, OH

Analytical Results

Desc. 1:	08/26/05	Laboratory ID:	304810624		
Desc. 2:	Swiss Composite	Condition Rec'd:	NORMAL		
Desc. 3:	Vats 1-14	Temp Rec'd (°C):	3.4		
<u>Analyte</u>	<u>Result</u>	<u>Units</u>	<u>Method Reference</u>	<u>Test Date</u>	<u>Loc.</u>
E. coli / Coliform - Petrifilm			SMEDP, 16th ed.	9/30/05	
Coliform-Petrifilm	<10	/g			
E. coli-Petrifilm	<10	/g			
PCR L. monocytogenes	Negative	/25g	AOAC 2003.12	9/30/05	

Amitha Miele

Laboratory Director


SILLIKER, Inc.
Ohio Laboratory

 2057 Builders Place
 Columbus, OH 43204
 614/ 486 0150 Fax 614/ 486 0151

CERTIFICATE OF ANALYSIS

COA No:	OHI-30888744-0
Supersedes:	None
COA Date	10/21/05
Page 1 of 1	

TO:

 Ms. Jennifer B. George
 Quality Assurance Manager
 Guggisberg Cheese Inc.
 5060 State Route 557
 Millersburg, OH 44654

Received From:	Millersburg, OH
Received Date:	10/19/05
P.O.# / ID:	SC
Location of Test: (except where noted) Columbus, OH	

Analytical Results

Desc. 1:	LS1	Laboratory ID:	304988014		
Desc. 2:	Swiss Composite	Condition Rec'd:	NORMAL		
Desc. 3:	09/15/05	Temp Rec'd (°C):	4.0		
<u>Analyte</u>	<u>Result</u>	<u>Units</u>	<u>Method Reference</u>	<u>Test Date</u>	<u>Loc.</u>
E. coli / Coliform - Petrifilm			SMEDP, 16th ed.	10/21/05	
Coliform-Petrifilm	<10	/g			
E. coli-Petrifilm	<10	/g			
PCR L. monocytogenes	Negative	/25g	AOAC 2003.12	10/21/05	

Amitha Miele

Laboratory Director



SILLIKER, Inc.
Ohio Laboratory
 2057 Builders Place
 Columbus, OH 43204
 614/ 486 0150 Fax 614/ 486 0151

CERTIFICATE OF ANALYSIS

COA No:	OHI-30888547-0
Supersedes:	None
COA Date	10/21/05
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TO:

Ms. Jennifer B. George
 Quality Assurance Manager
 Guggisberg Cheese Inc.
 5060 State Route 557
 Millersburg, OH 44654

Received From:	Millersburg, OH
Received Date:	10/19/05
P.O.# / ID:	SC
Location of Test: (except where noted) Columbus, OH	

Analyte

PCR L. monocytogenes

Result Units
 Negative /Sponge

Temp Rec'd (°C): 4.0

Method Reference Test Date Loc.
 AOAC 2003.12 10/21/05

Amitha Miele

Laboratory Director



SILLIKER, Inc.
Ohio Laboratory
 2057 Builders Place
 Columbus, OH 43204
 614/ 486 0150 Fax 614/ 486 0151

CERTIFICATE OF ANALYSIS

COA No:	OHI-30929830-0
Supersedes:	None
COA Date	11/18/05
Page 1 of 1	

TO:

Ms. Jennifer B. George
 Quality Assurance Manager
 Guggisberg Cheese Inc.
 5060 State Route 557
 Millersburg, OH 44654

Received From:	Millersburg, OH
Received Date:	11/16/05
P.O.# / ID:	SC
Location of Test: (except where noted)	Columbus, OH

Analytical Results

Desc. 1:	Environmental Sponges	Laboratory ID:	305221660
Desc. 2:	SC1	Condition Rec'd:	NORMAL
		Temp Rec'd (°C):	5.0
<u>Analyte</u>	<u>Result</u> <u>Units</u>	<u>Method Reference</u>	<u>Test Date</u> <u>Loc.</u>
Genus Listeria - ELFA	Negative /Sponge	AOAC 999.06	11/18/05
Desc. 1:	Environmental Sponges	Laboratory ID:	305221669
Desc. 2:	SC2	Condition Rec'd:	NORMAL
		Temp Rec'd (°C):	5.0
<u>Analyte</u>	<u>Result</u> <u>Units</u>	<u>Method Reference</u>	<u>Test Date</u> <u>Loc.</u>
Genus Listeria - ELFA	Negative /Sponge	AOAC 999.06	11/18/05
Desc. 1:	Environmental Sponges	Laboratory ID:	305221672
Desc. 2:	SC3	Condition Rec'd:	NORMAL
		Temp Rec'd (°C):	5.0
<u>Analyte</u>	<u>Result</u> <u>Units</u>	<u>Method Reference</u>	<u>Test Date</u> <u>Loc.</u>
Genus Listeria - ELFA	Negative /Sponge	AOAC 999.06	11/18/05
Desc. 1:	Environmental Sponges	Laboratory ID:	305221674
Desc. 2:	SC4	Condition Rec'd:	NORMAL
		Temp Rec'd (°C):	5.0
<u>Analyte</u>	<u>Result</u> <u>Units</u>	<u>Method Reference</u>	<u>Test Date</u> <u>Loc.</u>
Genus Listeria - ELFA	Negative /Sponge	AOAC 999.06	11/18/05
Desc. 1:	Environmental Sponges	Laboratory ID:	305221675
Desc. 2:	SC5	Condition Rec'd:	NORMAL
		Temp Rec'd (°C):	5.0
<u>Analyte</u>	<u>Result</u> <u>Units</u>	<u>Method Reference</u>	<u>Test Date</u> <u>Loc.</u>
Genus Listeria - ELFA	Negative /Sponge	AOAC 999.06	11/18/05

Amitha Miele

Laboratory Director